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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,746	02/09/2000	Robert J Winchester	57005-B/JPW/JSC	3022

7590

05/05/2003

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/500,746

Applicant(s)
Winchester et al.

Examiner
Ron Schwadron, Ph.D.

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 17, 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10, 13-15, 18, and 19 is/are pending in the application.
- 4a) Of the above, claim(s) 1-6, 8-10, and 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

1. Claims 18 and 19 are under consideration. Claims 7,11,12,16,17 have been canceled.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. Schols et al. teach a bicyclam (AMD3100) and said compound in a carrier/pharmaceutically acceptable carrier (eg. media used to dissolve said compound or PBS)(see page 147 and page 149, second column, first complete paragraph and Figure 2). Regarding the limitation "amount effective to treat rheumatoid arthritis", the amount used in School et al. was sufficient to block activation of the CXCR4 receptor and therefore could presumably used to treat rheumatoid arthritis. There is no disclosure in the specification as to what actual dosage of bicyclam/AMD3100 would be used to treat RA.

Regarding applicants arguments and the limitation "amount effective to treat rheumatoid arthritis", the amount used in School et al. was sufficient to block activation of the CXCR4 receptor and therefore could presumably used to treat rheumatoid arthritis. There is no disclosure in the specification as to what actual dosage of bicyclam/AMD3100 would be used to treat RA.

4. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by De Vreese et al. as evidenced by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. De Vreese et al. teach the bicyclam JM3100 and said compound in a carrier/pharmaceutically acceptable carrier (eg. media used to dissolve said compound)(see page 210 and section 2.3). Schols et al. disclose that JM3100 is another name for AMD3100 (see page 147, second column). Regarding the limitation "amount effective to treat rheumatoid arthritis", the amount used in De Vreese et al. was sufficient to inherently block CXCR4 receptor mediated activity and therefore could presumably be used to treat rheumatoid arthritis. There is no disclosure in the specification as to what actual dosage of bicyclam/AMD3100 would be used to treat RA.

Regarding applicants arguments and the limitation "amount effective to treat rheumatoid arthritis", the amount used in De Vreese et al. was sufficient to block CXCR4 receptor mediated activity and therefore could presumably be used to treat rheumatoid arthritis. There is no disclosure in the specification as to what actual dosage of bicyclam/AMD3100 would be used to treat RA.

5. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Murrer et al. (US Patent 5,021,409)

The recitation of an intended use carries no patentable weight in the instant product claims. The recitation of a method of making the claimed compound/composition carries no patentable weight in the instant product claims. Murrer et al. teach bicyclams in a carrier/pharmaceutically acceptable carrier (see column 1, third paragraph, column 2, penultimate paragraph and claims 7 and 8). Regarding the limitation "amount effective to treat rheumatoid arthritis", Murrer et al. teach a composition containing bicyclams at a dosage of 0.1 to 100 mg/kg. Since said dosage can be used to treat disease (wherein bicyclams inherently block CXCR4 mediated mechanisms) said dosage could presumably be used to treat rheumatoid arthritis. There is no disclosure in the specification as to what actual dosage of bicyclam/AMD3100 would be used to treat RA.

6. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Datema et al. as evidenced by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. Datema et al. teach the bicyclam JM3100 and said compound in a carrier/pharmaceutically acceptable carrier at a variety of different concentrations (see page 751, column 2). Schols et al. disclose that JM3100 is another name for AMD3100 (see page 147, second column). Regarding the limitation "amount effective to treat rheumatoid arthritis", the amount used by Datema et al. was sufficient to block CXCR4 receptor mediated activity in vivo (eg. HIV entry into cells wherein said entry is inherently mediated by CXCR4) and therefore could presumably be used to treat rheumatoid arthritis. There is no disclosure in the specification as to what actual dosage of bicyclam/AMD3100 would be used to treat RA.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to

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6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600 (662)

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644